

We claim:

1. A process of preparing ginseng fraction PQ<sub>2</sub>, the process comprising:
  - (a) combining American ginseng with a first solvent comprising an alcohol and heating the resulting solution at a temperature of about 80-100°C for a time period of about 2-4 hours to produce a first ginseng solution;
  - (b) thereafter separating the first ginseng solution to produce an alcohol/ginseng solution and a first ginseng residue;
  - 10 (c) thereafter combining the first ginseng residue with water and heating the resulting solution at a temperature of about 80-100°C for a time period of about 2-4 hours to produce a ginseng residue solution;
  - (d) thereafter separating the ginseng residue solution to produce a second ginseng residue and a first aqueous extract solution containing a first ginseng extract;
  - 15 (e) providing a second aqueous extract solution which comprises at least a part of the first ginseng extract, wherein in the second aqueous extract solution the proportion of the first ginseng extract to water is about 1:18 to 1:22;
  - 20 (f) thereafter combining the second aqueous extract solution with a second solvent comprising an alcohol, wherein the proportion of the second solvent to water is about 1:1 to 3:5, to produce a first precipitate and a first supernatant;
  - (g) thereafter combining the first supernatant produced in step 25 (f) with a third solvent comprising an alcohol, wherein the proportion of the third solvent to first supernatant is about 3:2 to 3:1, to produce a second precipitate and a second supernatant; and
  - (h) isolating the second precipitate to produce ginseng fraction

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PQ<sub>2</sub>.

2. The process of claim 1, wherein the alcohol in each of the first solvent, second solvent and third solvent independently comprises a saturated or unsaturated C<sub>1</sub>-C<sub>6</sub> alcohol.
- 5 3. The process of claim 1, wherein the alcohol in each of the first solvent, second solvent and third solvent independently comprises ethanol or methanol.
4. The process of claim 1, wherein in step (e) the second aqueous extract solution comprises at least a part of the first aqueous extract solution.
- 10 5. The process of claim 1, wherein in step (a) the resulting solution is heated for a time period of about 3 hours.
6. The process of claim 1, wherein in step (c) the resulting solution is heated for a time period of about 3 hours.
- 15 7. The process of claim 1, wherein in step (e) the proportion of the first ginseng extract to water is about 1:20.
8. The process of claim 1, wherein in step (f) the proportion of the second solvent to water is about 3:4.
- 20 9. The process of claim 1, wherein in step (g) the proportion of the third solvent to first supernatant is about 2:1.

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10. The process of claim 1, wherein in step (a) the first solvent and the ginseng are combined in a proportion of about 7-9 ml of first solvent per gram of ginseng.

11. The process of claim 1, wherein in step (a) the first solvent and  
5 the ginseng are combined in a proportion of about 8 ml of first solvent per gram of ginseng.

12. The process of claim 1, wherein in step (c) the water and the first ginseng residue are combined in a proportion of about 7-9 ml of water per gram of ginseng residue.

10 13. The process of claim 1, wherein in step (c) the water and the first ginseng residue are combined in a proportion of about 8 ml of water per gram of ginseng residue.

14. Ginseng fraction PQ<sub>2</sub>, produced according to the process of any of claims 1-13.

15 15. A process of preparing ginseng fraction PQ<sub>223</sub>, the process comprising:

(a) providing ginseng fraction PQ<sub>2</sub>, produced according to the process of any of claims 1-13;

20 (b) fractionating the ginseng fraction PQ<sub>2</sub> to produce a first elution fraction and a second elution fraction, wherein the first elution fraction corresponds to a carbohydrate peak observed between 35 and 50 ml of elution volume and the second elution fraction corresponds to a carbohydrate peak observed between 50 and 85 ml of elution volume,

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as determined by gel filtration chromatography using the following materials:

- (1) a chromatographic column containing a matrix of a spherical cross-linked co-polymer of allyl dextran and N,N'-methylenebisacrylamide, having a bed dimension of 16 × 600 mm, a bed volume of 120 ml, and a fractionation range (MW) of 5000 to 250,000 for globular proteins and 1000 to 80,000 for dextrans, and
- 5 (2) an elution buffer of Tris-HCl containing 0.1 N HCl and 0.3 M NaCl at a pH of 7.0; and
- 10 (c) isolating and combining the first elution fraction and the second elution fraction to produce ginseng fraction PQ<sub>223</sub>.

16. The method of claim 15, wherein ginseng fraction PQ<sub>2</sub> is fractionated using gel filtration chromatography.

17. Ginseng fraction PQ<sub>223</sub>, produced according to the process of  
15 claims 15 or 16.

18. A process of preparing ginseng fraction CVT-E002, the process comprising:

- (a) combining American ginseng with a first solvent comprising an alcohol in a proportion of about 7-9 ml of first solvent per gram of ginseng and heating the resulting solution at a temperature of about 80-100°C for a time period of about 2-4 hours, to produce a first ginseng solution;
- 20 (b) thereafter separating the first ginseng solution to produce an alcohol/ginseng solution and a first ginseng residue;
- 25 (c) thereafter combining the first ginseng residue with water in

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a proportion of about 7-9 ml of water per gram of ginseng residue and heating the ginseng residue solution at a temperature of about 80-100°C for a time period of about 2-4 hours, to produce a ginseng residue solution;

- 5           (d) thereafter separating the ginseng residue solution to produce a second ginseng residue and an aqueous extract solution containing a ginseng extract; and  
             (e) drying or concentrating the aqueous extract solution to produce ginseng fraction CVT-E002.

10       19. The process of claim 18, wherein in step (a) the first solvent and the sample are combined in a proportion of about 8 ml of first solvent per gram of sample.

15       20. The process of claim 18, wherein in step (c) the water and the first ginseng residue are combined in a proportion of about 8 ml of water per gram of ginseng residue.

21. The process of claim 18, wherein in step (a) the first ginseng solution is heated for a time period of about 3 hours.

22. The process of claim 18, wherein in step (c) the ginseng residue solution is heated for a time period of about 3 hours.

20       23. The process of claim 18, wherein the alcohol in the first solvent comprises a saturated or unsaturated C<sub>1</sub>-C<sub>6</sub> alcohol.

24. The process of claim 18, wherein the alcohol in the first solvent

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comprises ethanol or methanol.

25. Ginseng fraction CVT-E002, produced according to the process of any of claims 18-24.

26. A ginseng fraction, having a carbohydrate content which  
5 comprises about 2-6 mol% rhamnose, about 41-49 mol% galacturonic acid, about 12-18 mol% glucose, about 16-22 mol% galactose and about 12-19 mol% arabinose.

27. The ginseng fraction of claim 26, wherein the carbohydrate content comprises about 3-5 mol% rhamnose, about 43-47 mol%  
10 galacturonic acid, about 14-16 mol% glucose, about 18-20 mol% galactose and about 14-17 mol% arabinose.

28. The ginseng fraction of claim 26, wherein the carbohydrate content comprises about 4 mol% rhamnose, about 45 mol% galacturonic acid, about 15 mol% glucose, about 19 mol% galactose and about 15  
15 mol% arabinose.

29. A ginseng fraction, having a carbohydrate content which comprises about 3-8 mol% rhamnose, about 36-44 mol% galacturonic acid, about 2-7 mol% glucose, about 25-33 mol% galactose and about 17-25 mol% arabinose.

20 30. The ginseng fraction of claim 29, wherein the carbohydrate content comprises about 4-7 mol% rhamnose, about 37-42 mol% galacturonic acid, about 3-6 mol% glucose, about 27-32 mol% galactose

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- and about 19-24 mol% arabinose.
31. The ginseng fraction of claim 29, wherein the carbohydrate content comprises about 5 mol% rhamnose, about 39 mol% galacturonic acid, about 4 mol% glucose, about 29 mol% galactose and about 21  
5 mol% arabinose.
32. A ginseng fraction, having a carbohydrate content which comprises about 0.5-5 mol% rhamnose, about 11-22 mol% galacturonic acid, about 40-60 mol% glucose, about 10-19 mol% galactose and about 11-19 mol% arabinose.
- 10 33. The ginseng fraction of claim 32, wherein the carbohydrate content comprises about 1-3 mol% rhamnose, about 13-20 mol% galacturonic acid, about 42-57 mol% glucose, about 12-17 mol% galactose and about 13-17 mol% arabinose.
- 15 34. A pharmaceutical composition, comprising the ginseng fraction according to any one of claims 14, 17 and 25-33 in combination with a pharmaceutically acceptable carrier.
- 20 35. Use of a ginseng fraction according to any one of claims 14, 17 and 25-33, alone or in combination with another medicament, in the preparation of a pharmaceutical composition suitable for treating a condition characterized by low immunity.
36. Use of claim 35, wherein the condition is selected from the group consisting of common cold, influenza, chronic fatigue syndrome, AIDS

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and cancer.

37. Use of a ginseng fraction according to any one of claims 14, 17 and 25-33 to stimulate the production of IL-1, IL-6 and/or TNF- $\alpha$  in cells.

38. Use of a ginseng fraction according to any one of claims 14, 17  
5 and 25-33 to stimulate the *in vitro* or *in vivo* production of immunoglobulins.

39. Use of a ginseng fraction according to any one of claims 14, 17 and 25-33 to activate B-lymphocyte proliferation and antibody production therefrom.

10 40. A method of treating a condition characterized by low immunity in a patient in need thereof, comprising administering to the patient a condition treating effective amount of a ginseng fraction according to any one of claims 14, 17 and 25-33.

15 41. The method of claim 40, wherein the condition is selected from the group consisting of common cold, influenza, chronic fatigue syndrome, AIDS and cancer.

42. A process of preparing ginseng fraction PQ<sub>2</sub>A, the process comprising:

- (a) providing ginseng fraction PQ<sub>2</sub>, produced according to the  
20 process of any of claims 1-13;
- (b) fractionating the ginseng fraction PQ<sub>2</sub> to produce an elution fraction which corresponds to a carbohydrate peak observed between

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35 and 50 ml of elution volume, as determined by gel filtration chromatography using the following materials:

- (1) a chromatographic column containing a matrix of a spherical cross-linked co-polymer of allyl dextran and N,N'-methylenebisacrylamide, having a bed dimension of 16 × 600 mm, a bed volume of 120 ml, and a fractionation range (MW) of 5000 to 250,000 for globular proteins and 1000 to 80,000 for dextrans, and
- 5 (2) an elution buffer of Tris-HCl containing 0.1 N HCl and 0.3 M NaCl at a pH of 7.0; and
- 10 (c) isolating the elution fraction to produce ginseng fraction PQ<sub>2</sub>A.

43. Ginseng fraction PQ<sub>2</sub>A, produced according to the process of claim 42.

44. A process of preparing ginseng fraction PQ<sub>2</sub>B, the process comprising:

- (a) providing ginseng fraction PQ<sub>2</sub>, produced according to the process of any of claims 1-13;
- (b) fractionating the ginseng fraction PQ<sub>2</sub>B to produce an elution fraction which corresponds to a carbohydrate peak observed between 50 and 85 ml of elution volume, as determined by gel filtration chromatography using the following materials:
- 20 (1) a chromatographic column containing a matrix of a spherical cross-linked co-polymer of allyl dextran and N,N'-methylenebisacrylamide, having a bed dimension of 16 × 600 mm, a bed volume of 120 ml, and a fractionation range (MW) of 5000 to 250,000 for globular proteins and 1000 to 80,000 for dextrans, and
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(2) an elution buffer of Tris-HCl containing 0.1 N HCl and 0.3 M NaCl at a pH of 7.0; and

(c) isolating the elution fraction to produce ginseng fraction PQ<sub>2</sub>B.

5 45. Ginseng fraction PQ<sub>2</sub>B, produced according to the process of claim 44.

46. A process of preparing ginseng fraction PQ<sub>2</sub>C, the process comprising:

10 (a) providing ginseng fraction PQ<sub>2</sub>, produced according to the process of any of claims 1-13;

(b) fractionating the ginseng fraction PQ<sub>2</sub> to produce an elution fraction which corresponds to a carbohydrate peak observed between 95 and 110 ml of elution volume, as determined by gel filtration chromatography using the following materials:

15 (1) a chromatographic column containing a matrix of a spherical cross-linked co-polymer of allyl dextran and N,N'-methylenebisacrylamide, having a bed dimension of 16 × 600 mm, a bed volume of 120 ml, and a fractionation range (MW) of 5000 to 250,000 for globular proteins and 1000 to 80,000 for dextrans, and

20 (2) an elution buffer of Tris-HCl containing 0.1 N HCl and 0.3 M NaCl at a pH of 7.0; and

(c) isolating the elution fraction to produce ginseng fraction PQ<sub>2</sub>C.

47. Ginseng fraction PQ<sub>2</sub>C, produced according to the process of  
25 claim 46.

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48. A process of preparing ginseng fraction PQ<sub>2</sub>D, the process comprising:

- (a) providing ginseng fraction PQ<sub>2</sub>, produced according to the process of any of claims 1-13;
- 5 (b) fractionating the ginseng fraction PQ<sub>2</sub> to produce an elution fraction which corresponds to a carbohydrate peak observed between 120 and 250 ml of elution volume, as determined by gel filtration chromatography using the following materials:
- (1) a chromatographic column containing a matrix of a spherical cross-linked co-polymer of allyl dextran and N,N'-methylenebisacrylamide, having a bed dimension of 16 × 600 mm, a bed volume of 120 ml, and a fractionation range (MW) of 5000 to 250,000 for globular proteins and 1000 to 80,000 for dextrans, and
- 10 (2) an elution buffer of Tris-HCl containing 0.1 N HCl and 0.3 M NaCl at a pH of 7.0; and
- 15 (c) isolating the elution fraction to produce ginseng fraction PQ<sub>2</sub>D.

49. Ginseng fraction PQ<sub>2</sub>D, produced according to the process of claim 48.

- 20 50. A composition, comprising at least two of the following ginseng fractions:
- (a) ginseng fraction PQ<sub>2</sub>A, according to claim 43;
- (b) ginseng fraction PQ<sub>2</sub>B, according to claim 45;
- (c) ginseng fraction PQ<sub>2</sub>C, according to claim 47; and
- 25 (d) ginseng fraction PQ<sub>2</sub>D, according to claim 49.